**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**
**CAMDEN VICINAGE**

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| **IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION**<br><br>**This Document Relates to All Actions** | MDL No. 2875<br><br>Honorable Robert B. Kugler, District Court Judge<br><br>ORAL ARGUMENT REQUESTED |

**MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO PRECLUDE THE OPINIONS OF DEFENSE EXPERT ALI AFNAN, PH.D.**

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## INTRODUCTION

Plaintiffs' motion to exclude the expert opinions of Dr. Ali Afnan, a Ph.D. chemist and well-respected regulatory expert who spent years at the United States Food and Drug Administration ("FDA"), fails for three primary reasons.

***First***, plaintiffs misunderstand Dr. Afnan's role as a rebuttal expert. It is both permissible and entirely routine for a defense expert to critique the opinions offered by the other side's experts, whether or not he offers affirmative opinions of his own. Plaintiffs' effort to twist this ordinary practice into a sign of bias is without merit.

***Second***, plaintiffs' remaining critiques generally relate to Dr. Afnan's conclusions or to his interpretation of various documents, and therefore should be tested at trial in front of a jury, not by *Daubert* motion. Dr. Afnan followed a straightforward methodology, which consisted of reviewing company documents and literature to evaluate plaintiffs' experts' conclusions related to current good manufacturing practices ("cGMPs") at ZHP facilities, and that methodology has routinely been found admissible. Moreover, plaintiffs' disagreements with Dr. Afnan are all unavailing because they are based on misrepresentations of his deposition testimony.

***Third***, and finally, plaintiffs' three-line request to exclude "chemistry or toxicology opinions," does not actually identify the opinions that they wish to exclude, and it is not the responsibility of the Court (or defense counsel) to hunt

through Dr. Afnan's report to identify them. In any event, Dr. Afnan has a Ph.D. in chemistry. While he has not been offered as an expert chemist or toxicologist, he is more than qualified to review scientific literature as necessary to inform his cGMP opinions.

## BACKGROUND

Dr. Ali Afnan has a degree in industrial chemistry and earned his Ph.D. in the subfield of instrumentation and analytical science from the University of Manchester Institute of Science and Technology in 1989. (*See* Am. Rep. of Ali Afnan, Ph.D. ("Afnan Am. Rep.") ¶ 4, Jan. 11, 2023 (Pls.' Br. Ex. 13).) Since then, he has spent more than 30 years working in the pharmaceutical industry, including with major pharmaceutical manufacturers and with the FDA. (*See id.* ¶ 2.) Dr. Afnan worked as a Senior Technologist at AstraZeneca from 1993 through 2003, when he joined the FDA as a senior staff fellow and policy advisor to the Director of the Office of Pharmaceutical Science. (*See id.* ¶¶ 6-7.) During his time at the FDA, Dr. Afnan helped draft the Process Validation Guideline and Process Analytical Technology Guideline, which are extensively used in the industry. (*See id.* ¶ 7.) He also oversaw regulatory applications, including by assessing the review process, training reviewers, and participating in inspections. (*See id.* ¶ 8.) During his time at the FDA, Dr. Afnan won several awards for his outstanding work. (*See id.* ¶ 12.)

Dr. Afnan is the author of more than 30 publications related to pharmaceutical manufacturing and regulation, a member of the editorial board for *Contract Pharma Magazine*, and a former contributing editor to *Pharmaceutical Manufacturing*. (*See id.* ¶ 13.) From 2006 to 2010, he served as an adjunct professor at the Duquesne University Graduate School of Pharmaceutical Sciences, where he taught courses related to pharmaceutical manufacturing processes and regulatory requirements. (*See id.* ¶ 11.)

Dr. Afnan was retained to "evaluate and respond to opinions offered by Plaintiffs' experts . . . regarding ZHP's compliance with FDA requirements, including [c]GMPs, in connection with its manufacture of [a]ctive [p]harmaceutical [i]ngredient ("API") for certain valsartan-containing drugs." (*Id.* ¶ 16.) In particular, he responds to Drs. Bain, Hecht, Najafi and Plunkett. To do so, he reviewed a wide variety of materials, including internal ZHP documents and fact witness depositions, along with scientific literature, FDA and other national and international regulatory rules and guidance, and the reports and depositions of other expert witnesses. (*See* Afnan Am. Rep., App. B (Materials Reviewed & Considered (Amended & Supplemental)) (attached as Ex. 1 to the Certification of Jessica Davidson ("Davidson Cert.")).) Based on his review of these materials, Dr. Afnan concluded that "[c]ontrary to Plaintiffs' experts' assertions," ZHP complied with cGMP, including standards set by the "United States Pharmacopeia ('USP') and

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ('ICH')." (Afnan Am. Rep. ¶ 18.) Among other things, Dr. Afnan concluded that "ZHP conducted appropriate risk assessments," that "neither industry nor regulators were aware that NDMA or NDEA could form" from the processes ZHP used, and that ZHP performed appropriate testing and responded appropriately to the discovery of nitrosamines in 2018." (*Id.* ¶¶ 19-22.) Dr. Afnan also evaluated the FDA's post hoc observations and concluded that they "do not establish non-compliance with [c]GMPs." (*Id.* ¶ 23.)

Although the opinions in Dr. Afnan's report are supposedly the target of the motion to exclude, his report is not cited a single time in plaintiffs' so-called statement of facts, and is cited just twice in the entire brief (once misleadingly and without a pincite). (*See generally* Pls.' Br.) Instead, plaintiffs' brief distorts the substance of Dr. Afnan's testimony and criticizes his conclusions. None of this justifies exclusion of his opinions.

## ARGUMENT

The relevant standard for evaluating the admissibility of expert testimony is laid out in greater detail in Defendants' Opposition to Plaintiffs' Motion to Preclude the Opinions of Dr. Fengtian Xue and incorporated herein by reference. (*See* Defs.' Mem. in Opp'n to Pls.' Mot. to Preclude Ops. of Def. Liability Expert Fengtian Xue, Ph.D. at 11-30, filed concurrently herewith.) As set forth below, Dr. Afnan's

opinions easily satisfy those standards. Plaintiffs' arguments to the contrary misunderstand the nature of a defense rebuttal expert, challenge conclusions rather than methodology, and misrepresent the record.

## I. DR. AFNAN OFFERS PROPER REBUTTAL OPINIONS.

Plaintiffs complain that Dr. Afnan "admitted" his "approach" "was limited to responding to the reports of the Plaintiffs' experts" (Pls.' Br. at 14), but "[i]t is the proper role of rebuttal experts to critique plaintiffs' expert[s'] methodologies and point out potential flaws in the plaintiff[s'] experts' reports," *Winn-Dixie Stores, Inc. v. E. Mushroom Mktg. Coop.*, No. 15-6480, 2021 WL 2352016, at *14 (E.D. Pa. June 9, 2021) (citation omitted). Rebuttal testimony is especially appropriate when offered by a defense expert who can "help the jury to evaluate testimony by plaintiff[s'] expert [on] an issue on which plaintiff[s bear] the burden of proof." *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 786 (3d Cir. 1996) (for such experts, "the test is different"); *see, e.g., In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 285 (E.D.N.Y. 2007) ("[D]efendants' experts have a less demanding task, since they have no burden to produce models or methods of their own; they need only attack those of plaintiffs' experts.").

In keeping with these principles, courts in this circuit, and around the country, routinely admit expert testimony focused on critiquing the analysis put forward by experts from the other side, whether or not the experts offer affirmative opinions of

their own. *See, e.g.*, *Winn-Dixie*, 2021 WL 2352016, at *14-15 ("[A] rebuttal expert witness[] may criticize other experts' theories and calculations without offering alternatives.") (citation omitted); *United States v. Velasquez*, 64 F.3d 844, 848, 851 (3d Cir. 1995) (reversing exclusion of rebuttal testimony that would have helped the jury "properly weigh the testimony" of opposing expert); *APEX Fin. Options, LLC v. Gilbertson*, No. 19-0046-WCB-SRF, 2022 WL 613347, at *3 (D. Del. Mar. 1, 2022) ("[A]s a rebuttal witness it was enough for [an expert] to critique [the opposing party's expert's] analysis; it was not necessary for him to offer an alternative approach."); *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1368 (N.D. Fla. 2018) ("entirely appropriate" for defendants' experts to offer "essentially, critiques of [p]laintiffs' experts' evidence, methodologies, and conclusions").

Dr. Afnan, who has a Ph.D. in chemistry and a background working for both pharmaceutical companies and the FDA, reviewed plaintiffs' experts' reports and depositions along with materials on which those experts purport to rely, such as ZHP documents and statements, and evaluated those materials by citing to regulatory and industry standards as well as scientific literature. That he did not "independently evaluate ZHP's application of cGMPs . . . in the development and use of its manufacturing processes" (Pls.' Br. at 14), is a consequence of the nature of his role and—at absolute most—fodder for cross-examination.

In an attempt to twist the role of a rebuttal witness, plaintiffs assert that Dr. Afnan "admitted that he was brought in by ZHP to refute the Plaintiffs' experts' opinions, and that is all he attempted to do, with no objectivity whatsoever." (Pls.' Br. at 2; *see also id.* at 14 ("result[-]driven approach . . . which he candidly admitted was limited to responding to the reports of the Plaintiffs' experts").) In fact, Dr. Afnan testified to precisely the opposite. At his deposition, plaintiffs' counsel asked Dr. Afnan whether he understood his "role to be to come up with arguments to defend ZHP?" (Dep. of Ali Afnan, Ph.D. ("Afnan Dep.") 139:15-17, Feb. 8, 2023 (Pls.' Br. Ex. 1).) Dr. Afnan responded: "That ***was not*** how I have approached this"; instead, he "assess[ed]" plaintiffs' experts' opinions "for correctness" (*id.* 139:20-140:1 (emphasis added)), which is exactly what a rebuttal expert is supposed to do.

## II. DR. AFNAN'S METHODOLOGY IS PROPER.

Plaintiffs also argue that Dr. Afnan "fails to identify or describe a methodology" (Pls.' Br. at 14), but Dr. Afnan explained that he reviewed documentary and testimonial evidence, regulatory and industry standards, and scientific literature, and applied his substantial experience, to reach his conclusions regarding ZHP's practices and plaintiffs' experts' opinions. (*See* Afnan Am. Rep. ¶ 17 ("My opinions in this case are based on my review of the materials listed in Appendix B, as well as my considerable experience in the field of FDA regulation.

My opinions are also informed by an interview I conducted . . . .").)[1] This is an entirely conventional and well-accepted methodology. *See, e.g.*, *United States ex rel. Penelow v. Janssen Prods., LP*, No. 12-7758 (ZNQ) (LGH), 2022 WL 94535, at *17-18 (D.N.J. Jan. 10, 2022) (admitting testimony from expert who reviewed "hundreds of documents," and regulatory and industry guidance in light of "professional experience and expertise") (citations omitted); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, MDL No. 2445, 2020 WL 6887885, at *36-37 (E.D. Pa. Nov. 24, 2020) (testimony regarding cGMPs based on expert's "review of documents and application of her experience" was admissible). And while plaintiffs also complain that Dr. Afnan supposedly ignored certain materials and take issue with his conclusions, those are matters for cross-examination, not *Daubert*, and are, in any event, meritless, as explained below.

### A. Plaintiffs' Complaints That Dr. Afnan Did Not Review Certain Materials Are Meritless.

Plaintiffs contend that Dr. Afnan ignored ZHP's internal procedures, misinterpreted ICH guidance on unknown impurities, failed to address the

[1] Some of plaintiffs' experts described their methods in much the same manner. (*See, e.g.*, Report of Ramin "Ron" Najafi, Ph.D. at 2, Oct. 31, 2022 (ECF No. 2292-6) ("My opinions are based on my education, practice, and experience, weighing the evidence, and on generally accepted practices in the field of chemistry and pharmaceutical industry, FDA guidance and regulations as well as industry standards and peer reviewed scientific literature").)

possibility that commercially purchased DMF contained impurities, and did not consider statements by the FDA and others. Even if these contentions were accurate, they would be fodder for cross-examination, not a basis for exclusion. *See*, *e.g.*, *Penelow*, 2022 WL 94535, at *17-18 ("failure or unwillingness to respond to" certain evidence "is an issue for cross examination"). As explained below, however, they are not accurate at all.

1. Dr. Afnan Considered ZHP Operating Procedures Relevant To His Rebuttal Opinions.

Plaintiffs contend that Dr. Afnan's opinions are flawed because he "admitted" that he did not "apply ZHP's internal standard operating procedures," "which equate[] to ZHP's quality system." (Pls.' Br. at 15.) But Dr. Afnan made no such admission at his deposition, and his expert report is to the contrary.

At Dr. Afnan's deposition, plaintiffs' counsel asked him to recite from memory every standard applicable to ZHP, including any internal "standard operating procedures that applied to ZHP in its development and manufacture of valsartan." (Afnan Dep. 37:16-21.) In response, Dr. Afnan discussed some of the many FDA standards addressed in his report, but noted that he did not have "the list of ZHP's SOPs" in front of him. (*Id.* 38:10-40:8.) In that context, he acknowledged that he "was not tasked with assessing ***all*** the [c]GMPs of ZHP" and that reciting every single SOP would be "beyond the scope of his assignment." (*Id.* 40:4-15 (emphasis added).) That is no surprise, since Dr. Afnan's role was to evaluate

plaintiffs' experts' assertions that ZHP violated certain cGMP requirements, a task that implicated only specific internal SOPs.

Dr. Afnan's report shows that he did review ZHP SOPs that were relevant to his opinions. For instance, he discussed "Standard Management Procedure ('SMP')-018," which represented "ZHP's internal procedure for approving the manufacturing changes at issue," at some length. (Afnan Am. Rep. ¶¶ 147-148.) And he specifically reviewed the two SOPs that plaintiffs' brief claims "should have been considered": the "Guideline for Genotoxic Impurity Evaluation" (ZHP01447235), and "SMP-023, titled: Quality Risk Management." (Pls.' Br. at 16-17.) Both documents were discussed in the report of plaintiffs' expert Dr. Susan Bain, and Dr. Afnan reviewed both as part of his evaluation of her opinions. (*See* Afnan Am. Rep., App. B at 1 (including in list of materials considered "Expert Report of S. Bain, dated Oct. 31, 2022, ***and all documents cited therein***") (emphasis added).) Notably, plaintiffs' counsel chose not to ask about these documents at Dr. Afnan's deposition. And plaintiffs have no basis to suggest that Dr. Afnan failed to review any ***relevant*** SOPs.

2. Dr. Afnan Properly Interpreted ICH Guidance On Impurity Thresholds.

Plaintiffs' criticism of Dr. Afnan's opinion that cGMPs did not require ZHP to identify unknown impurities below a certain threshold also misstates the record. Plaintiffs acknowledge that Dr. Afnan "relies on ICH Q3A" for his opinion that

unknown impurities of less than 0.1% need not be tested, but they claim that Dr. Afnan "agreed that the language of the [ICH] guidance" allowing certain unidentified impurities "exempted . . . NDMA and NDEA." (*See* Pls.' Br. at 17-18.) Dr. Afnan's testimony does not support plaintiffs' assertion. Dr. Afnan explained that the applicability of ICH guidance depends on the impurities that were expected, not on those ultimately discovered. (*See* Afnan Dep. 230:5-235:10.) And as Dr. Afnan has explained at length, neither NDMA nor NDEA could have been expected. Plaintiffs also claim that Dr. Afnan admitted that ZHP failed to comply with other portions of Q3A related to raw materials. (*See* Pls.' Br. at 17.) But his testimony was precisely the opposite: that ZHP ***did*** comply with the provision. (*See* Afnan Dep. 309:15-310:1.)

Plaintiffs' contention that Dr. Afnan "ignored the FDA Guidance for Industry, Genotoxic and Carcinogenic Impurities in Drug Substances and Products[:] Recommended Approaches" (Pls.' Br. at 19) is similarly meritless. Dr. Afnan discussed this document, and why he disagreed with plaintiffs' experts' opinions that ZHP violated it, in his report. (*See* Afnan Am. Rep. ¶¶ 155-160.) The related suggestion that Dr. Afnan was "unwilling or unable to state whether he considered" the Guidance at his deposition (Pls.' Br. at 20) is likewise false. Dr. Afnan was shown a document, which he explained was a non-final draft and in any event, expressly stated that it does not set forth any binding requirements in industry

generally. (*See* Afnan Dep. 327:23-328:11.) He further explained that, even on its own terms, the draft guidance did not require ZHP to test for NDMA or NDEA because neither ZHP, nor anyone else in the industry, nor the FDA, "knew about the [possible] formation . . . of these mutagenic substances." (*Id.* 339:12-340:2.)

3. Dr. Afnan Did Not Address The Possibility That ZHP Violated CGMPs By Failing To Test Raw Materials Because Plaintiffs' Experts Never Raised It.

Plaintiffs also fault Dr. Afnan for supposedly failing to address "the potential introduction of DMA as an impurity of the commercially[-]purchased DMF." (Pls.' Br. at 21 (capitalization altered).) This criticism once again misunderstands his role. As detailed above, Dr. Afnan's role was not to determine the root cause of nitrosamine contamination; it was to evaluate plaintiffs' experts' opinions on ZHP's cGMP compliance. Dr. Afnan therefore had no reason to address theories unless and until plaintiffs' experts advanced them. *See, e.g.*, *Winn-Dixie*, 2021 WL 2352016, at *14 (role of rebuttal expert is to "criticize other experts' theories and calculations without offering alternatives") (citation omitted).

In their reports, plaintiffs' experts never offered the opinion that ZHP violated cGMPs by failing to identify DMA as an impurity in purchased DMF, or by failing to identify any other impurities in purchased raw material, such as DEA in TEA.[2]

[2] DMA and TEA can undergo nitrosation reactions to form NDMA and NDEA, respectively.

As explained in detail in defendants' motion to partially exclude the opinions of plaintiffs' experts Drs. Hecht and Najafi, neither of them properly disclosed opinions related to DMF contamination in their reports, which, at most, mentioned the issue in a single passing sentence. (*See* ECF No. 2292-1 ("Hecht/Najafi Br.") at 18-21.) Instead, their reports focused on the assertion that ZHP should have known that DMA and DEA would be ***created*** as a result of the manufacturing process. The same is true of the reports offered by Drs. Bain and Plunkett. (*See, e.g.*, Rep. of Susan Bain at 10, Oct. 31, 2022 (ECF No. 2284-3) ("risk assessment of DMF did not specifically evaluate whether DMF was degrading" into DMA); *id.* at 23 ("failure to perform scientific research into the potential decomposition of products of DMF"); Rep. of Laura M. Plunkett, Ph.D., DABT at 21, Oct. 31, 2022 (ECF No. 2285-3) ("did not consider . . . DMF degradants").)

By the time plaintiffs' experts advanced the contamination theory at their depositions (Hecht/Najafi Br. at 18-21), Dr. Afnan's report had already been submitted. Plaintiffs cannot claim that his report evinces an unreliable methodology because it failed to rebut a theory that had not yet been advanced.[3]

[3] Notably, defendants initially expected to produce Dr. Afnan's report after plaintiffs' experts' depositions, which would have allowed him to address any newly-disclosed opinions, but were told by plaintiffs "[t]hat is not how we . . . proceed[] in this litigation." (Email from A. Slater to J. Davidson Miller, Nov. 2, 2022 (Ex. 2 to Davidson Cert.).)

In any event, plaintiffs are wrong that Dr. Afnan "was completely unaware of" possible raw material contamination "and had given no consideration to it." (Pls.' Br. at 22.) In the deposition passage plaintiffs cite, Dr. Afnan simply reiterated that he had not considered the possibility of raw material contamination because, as discussed, "the scope of [his] work was to look at the [P]laintiff[s'] experts[']reports." (Afnan Dep. 114:18-21 (cited in Pls.' Br. at 22).) When further questioned at his deposition about plaintiffs' new theory that the raw materials used by ZHP contained reactive impurities, however, he explained that "there are no 100 percent pure compounds" and that ZHP fulfilled its obligation to "demonstrate looking for potential impurity formations." (*Id.* 141:9-10, 142:14-23; *see id.* 142:24-143:1 ("what they were supposed to do they did do"), 153:3-11 ("ZHP looked at the potential risks due to the potential impurities in the process . . . . ZHP did do what it was supposed to do.").)

4. Dr. Afnan Properly Considered Statements By The FDA And Others.

Finally, plaintiffs offer a laundry-list of additional documents, from the FDA and others, that they claim Dr. Afnan should have considered. In fact, he considered every single one.

***First***, plaintiffs claim that Dr. Afnan "never deal[t] with the contents of" one FDA warning letter that was sent in November 2018 and referenced cGMP violations. (Pls.' Br. at 24.) But Dr. Afnan ***did*** discuss the FDA's warning letter at

considerable length and explained why he did not agree that it demonstrated cGMP violations. (Afnan Am. Rep. ¶¶ 194-205, 209-210.) Specifically, Dr. Afnan opined that warning letters are "informal and advisory" (*id.* ¶ 196) and thus do not "constitute final, binding determinations as to [c]GMP" (*id.* ¶ 194; *see id.* ¶ 195). That is especially so where, as here, the observations were "made in hindsight" based on an investigation conducted after the product had been removed from the market. (*Id.* ¶ 210; *see id.* ¶¶ 200-205.) Dr. Afnan likewise accounted for the FDA's letter in rejecting plaintiffs' experts' opinions that the valsartan API was adulterated. He did so both in his report (*see id.* ¶¶ 207-210), and, as plaintiffs obliquely admit, at his deposition (*see* Pls.' Br. at 24, 25 (citing Afnan Dep. 53:9-57:2, 369:22-371:5)).[4]

***Second***, plaintiffs assert that Dr. Afnan "failed to reliably contend" with statements made in a draft Deviation Investigation Report that ZHP created after the recall. (Pls.' Br. at 26.) But Dr. Afnan discussed ZHP's final Deviation Investigation Report in his report (Afnan Am. Rep. ¶ 171), and his list of reliance materials demonstrates that he had reviewed the draft version referenced by plaintiffs, since it was among the documents Dr. Bain had cited in her report. (*See*

[4] The same is true of the FDA's import alert. (*See* Pls.' Br. at 26.) Dr. Afnan considered the alert and concluded that it did not "contain backward-looking conclusions that ZHP had failed to comply with [c]GMP in connection with the manufacture and testing of valsartan API in the preceding decade." (Afnan Am. Rep. ¶¶ 204-205.)

Afnan Am. Rep., App. B at 1.) The draft version, unlike the final version, stated that ZHP had failed to identify NDMA "[d]ue to . . . insufficient study and understanding of potential genotoxic impurities." (Pls.' Br. at 26 (citation omitted).) At his deposition, Dr. Afnan explained exactly why he discounted this statement from the rough draft: "It doesn't mean it's correct. I don't know who wrote that. I don't know whether the quality [assurance] organization of the site agreed with that statement." (Afnan Dep. 377:5-10.) Dr. Afnan also explained that, like the FDA warning letter, both the draft and final versions of the Deviation Investigation Report were written "with a 20/20 hindsight [knowing that] NDMA was present in valsartan."[5] (*Id.* 111:10-22.)

***Third***, plaintiffs claim that Dr. Afnan's opinion is undermined by a passage from the USP that calls for additional tests in certain circumstances, and that Dr. Afnan "admitted" it "speaks to the facts here." (Pls.' Br. at 24; *see* USP General Notices & Requirements, Revision Bulletin § 5.60 (Apr. 1, 2015) (Pls.' Br. Ex. 32).) Not so. When asked directly whether that passage of the USP required additional

[5] Plaintiffs baldly assert that Dr. Afnan's opinion that cGMP violations should not be judged in hindsight is "so flawed that it requires no analysis." (Pls.' Br. at 28.) In fact, it is consistent with the principle that manufacturers are required to "follow 'good manufacturing practices'—not perfect manufacturing practices," *In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig.*, No. 1:01-CV-9000, 2009 WL 10664164, at *12 (N.D. Ohio Feb. 25, 2009), a standard that necessarily depends on the state of scientific knowledge.

non-monograph tests whenever a company "change[s] the processing methods or introduce[s] external sources," Dr. Afnan replied "No." (Afnan Dep. 390:3-19.) He also repeatedly explained that, unlike other portions of the USP, the portion plaintiffs cited was "advisory" and "not binding," and that other protocols provided "more specific" guidance. (*Id.* 189:2-11.)[6]

In short, every one of plaintiffs' attacks on Dr. Afnan is flatly contrary to the record. Thus, even if they were relevant to the limited *Daubert* inquiry, and they are not, they would fail to justify his exclusion.

### B. Plaintiffs' Disagreement With Dr. Afnan's Conclusions Is Not A Basis For Exclusion.

Plaintiffs also attack Dr. Afnan's conclusions, calling them "fanciful," "incorrect," "obviously inaccurate," "hopelessly counterintuitive," or somehow "legally impermissible." (Pls.' Br. at 2, 12, 24, 25, 30.) But in evaluating the admissibility of expert testimony, the Court must "focus[] on principles and methodology and not on the conclusions they generate" because "analysis of the conclusions themselves is for the trier of fact." *Kannankeril v. Terminix Int'l, Inc.*,

[6] Plaintiffs' remaining arguments, which they advance in entirely perfunctory fashion, are even less availing. For instance, plaintiffs accuse Dr. Afnan of "circular reasoning," contending that he relied on the fact that ZHP did not identify NDMA or NDEA to hold that it could not have done so. (Pls.' Br. at 27.) But their own block quote shows that the only person who advanced this allegedly circular theory was plaintiffs' counsel in a deposition question. (*See id.* (quoting Afnan Dep. 361:22-362:6).)

128 F.3d 802, 807 (3d Cir. 1997). The inquiry under Rule 702 and *Daubert* "is essentially results-agnostic." *Dzielak v. Whirlpool, Co.*, No. 2:12-0089 (KM) (JBC), 2017 WL 1034197, at *10 (D.N.J. Mar. 17, 2017); *see, e.g.*, *Winn-Dixie*, 2021 WL 2352016, at *11 (declining to exclude expert opinion "simply because [the opposing party] deem[s] his conclusions counterintuitive"); *UGI Sunbury LLC v. A Permanent Easement for 0.4308 Acres*, No. 3:16-CV-00794, 2021 WL 5140050, at *9 (M.D. Pa. Nov. 4, 2021) ("arguments concern[ing] only the sufficiency of the evidence [expert] relied on (and the conclusions drawn therefrom) . . . are not valid bases for excluding [his] testimony or reports").[7]

None of plaintiffs' authority supports the idea that disagreement with an expert's conclusions or his or her interpretation of evidence provides a valid basis for excluding the expert. *In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, 858 F.3d 787 (3d Cir. 2017) (cited in Pls.' Br. at 12, 13, 17) and *In re Mirena IUS Levonorgestrel-Related Products Liability Litigation (No. II)*, 341 F. Supp. 3d 213 (S.D.N.Y. 2018) (cited in Pls.' Br. at 14, 17), both involved experts who purported to use the Bradford-Hill methodology to reach affirmative opinions

[7] Plaintiffs quote the Court's statement that "'[i]t is . . . incontrovertible . . . that the contamination [of valsartan] resulted from [D]efendants' non-compliance [with] cGMPs at some level." (Pls.' Br. at 1 (quoting ECF No. 2261, at 21).) But the Court made that statement in the context of class certification; it has never found cGMP violations as a matter of law or removed the issue from the purview of a jury.

that certain medications caused disease in the face of universal scientific consensus to the contrary. But it was not the experts' far-fetched conclusions that justified exclusion. Instead, both cases focused on the experts' haphazard and unscientific methodologies. *See, e.g.*, *Zoloft*, 858 F.3d at 796-97 (holding that "[t]he specific ***way*** an expert conducts [a general causation] analysis must be reliable" and excluding expert who "did not explain how he drew conclusions" and used techniques that he "admitted" were not "scientifically rigorous"); *Mirena*, 341 F. Supp. 3d at 248 (stating that "expert's application of the individual [Bradford-Hill] criteria be performed with proper rigor" and excluding expert with a methodology so "obscure" that it "effectively disable[d] a finder of fact from critically evaluating his work").

*Player v. Motiva Enterprises LLC*, No. 02-3216(RBK), 2006 WL 166452 (D.N.J. Jan. 20, 2006), is even further afield. In that case, an expert (whom this Court had already found unqualified) offered an affirmative opinion about the value of certain property. This Court found that purporting to place a value on property "without discussing, or even recognizing, the extent to which the property was actually contaminated" was entirely "arbitrary" and, thus, inadmissible. *Id.* at *7, *8.

Put simply, plaintiffs urge the Court to reject Dr. Afnan's interpretation of certain evidence. But as this Court acknowledged in *Player*, Rule 702 is not a license

to "substitute [its] opinions for those of [the] expert." *Id.* at *6. Rather, it is up to the jury to decide which experts' opinions to accept.

## III. DR. AFNAN IS QUALIFIED TO COMMENT ON CHEMISTRY ISSUES RELEVANT TO HIS CGMP OPINIONS.

Plaintiffs also argue—in three sentences and without citing any authority—that Dr. Afnan "cannot offer opinions in the fields of organic chemistry or toxicology" because he is not qualified to do so. (*See* Pls.' Br. at 14.) That passing argument has no support in either law or fact.

To start, plaintiffs do not point to a single organic chemistry or toxicological opinion of Dr. Afnan's that should be excluded. Instead, they "essentially ask[] the [c]ourt to rule in a vacuum, without providing the specific content of" the opinions they want excluded or the context in which those opinions are offered. *McBroom v. Ethicon, Inc.*, No. CV-20-02127-PHX-DGC, 2021 WL 2709292, at *11 (D. Ariz. July 1, 2021).

"[W]hether specific opinions are outside the scope of [an expert's] expertise . . . cannot be determined in the abstract." *Hart v. Mountain W. Farm Bureau Mut. Ins. Co.*, No. 19-08-M-DWM, 2019 WL 7020147, at *5 (D. Mont. Dec. 20, 2019). Accordingly, courts routinely reject requests for "speculative or advisory rulings" on expert testimony. *In re Ethicon, Inc.*, No. 2:12-MD-02327, 2016 WL 4536885, at *5 (S.D. W. Va. Aug. 30, 2016) (declining to exclude expert opinions where "the parties ask[ed] the court to prevent experts from offering" testimony "without

identifying the expert testimony to be excluded"); *see also, e.g.*, *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 4165021, at *3 (N.D. Ohio Sept. 3, 2019) (refusing to "issue an advisory ruling excluding unspecified" opinions where defendants "fail[ed] to identify the specific opinions or the particular testimony of [the expert] they s[ought] to exclude" and instead made "generic complaints about the types of opinions and categories of testimony").

In any event, Dr. Afnan possesses degrees in chemistry, in addition to being an expert in FDA regulations governing the manufacture of pharmaceuticals and cGMP compliance. (*See* Afnan Dep. 158:3-13; Afnan Am. Rep., App. A (Afnan CV) at 2-3 (Ex. 3 to Davidson Cert.).) As a result, and like plaintiffs' expert Stephen S. Hecht, who similarly has a Ph.D. in chemistry (*see* Report of Stephen Hecht, Ph.D. at 2, July 6, 2021 (ECF No. 2292-7)), Dr. Afnan "understand[s] sufficiently about chemistry to opine on the subject" and is qualified to offer opinions regarding scientific matters relevant to cGMP issues (Afnan Dep. 158:3-13).

For example, as he explained at his deposition, Dr. Afnan can look at the materials Dr. Xue referenced and "verif[y]" that certain of his statements on the relevant chemistry were correct, as opposed to blindly relying on Dr. Xue's opinions. (Afnan Dep. 155:20-158:13.) Dr. Afnan can also apply his understanding of the chemistry literature to inform his cGMP opinions, such as his opinion that "ZHP's scientists did not have a reasonable scientific basis to expect that NDMA or NDEA

could form" and, thus, were not required to test for nitrosamines. (Afnan Am. Rep. ¶ 141.) There is nothing impermissible about Dr. Afnan using his education to comprehend the findings of another expert and to apply them to his own more specific expertise, and plaintiffs have not pointed to any portion of Dr. Afnan's report or deposition in which he exceeds those bounds. *See Botey v. Green*, No. 3:12-CV-1520, 2017 WL 2535735, at *2 n.2 (M.D. Pa. June 8, 2017) (rejecting plaintiff's argument that "because [expert] is a psychologist, he is not qualified to offer any opinions regarding [plaintiff]'s physical health" where plaintiff did "not point to any part of [expert]'s [r]eport where he offers an opinion as to [plaintiff]'s physical health"; rather, the expert's opinions on physical health were "limited to summaries and observations of other doctors' findings").

Accordingly, plaintiffs' vague and conclusory argument that Dr. Afnan cannot offer chemistry opinions should be rejected.

## CONCLUSION

For the foregoing reasons, the Court should deny plaintiffs' motion to preclude Dr. Afnan's opinions in its entirety.

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on April 11, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson*
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